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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,814	04/19/2005	Masaomi Iyo	268519US0PCT	4204

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EXAMINER	
HAYES, ROBERT CLINTON	
ART UNIT	**PAPER NUMBER**
1649	

NOTIFICATION DATE	DELIVERY MODE
04/01/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/528,814	IYO ET AL.	
	Examiner	Art Unit	
	Robert C. Hayes, Ph.D.	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-10 and 13* is/are pending in the application.

4a) Of the above claim(s) *4-6 and 13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *4-10 and 13* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/21/05;1/9/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II (method claims 7-10) in the reply filed on 10/24/07 is acknowledged. The traversal is on the ground(s) that "[r]estriction is only proper if the claims of the restricted are independent or patentably distinct and there would been serious burden placed on the Examiner if restriction is not required". This is not found persuasive because of the reasons made of record in Paper No: 20070924, and because even though the International Preliminary Examination report chose to not require a lack of unity, no special technical feature still exists for Group I, as illustrated by the multiple X references listed in the Search Report. Therefore, no unity of invention exists, because the claimed invention did not provide a contribution over the prior art, and because PCT Rule 13 does not provide for multiple products or methods within a single application, especially when the technical feature of the Group I invention is not a special technical feature. The requirement is still deemed proper and is therefore made FINAL.

Claims 4-6 & 13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/23/07.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The specification describes BDNF on page 3 as being known in the art in the 1990s. In other words, one human BDNF molecule is structurally well known in the art, which was isolated by Barde et al. in 1982. Antibodies against this human BDNF molecule were also known in the art, as illustrated on page 13 of the specification. In contrast, the claim language of "a" brain-derived neurotrophic factor implies multiple BDNF molecules, which have not been described within the instant specification.

Second, the specification described only the two eating disorders, anorexia nervosa and bulimia nervosa. No other eating disorders are described. Nor is it known, or described, if any other eating disorders are related to altered/decreased BDNF levels in blood. Thus, the current claims do not reasonably meet the written description requirements under 112, first paragraph.

Accordingly, *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, 1117, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, *as of the filing date sought*, he or she was in possession *of the claimed invention*". "The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed* [emphasis added]".

3. Claims 7-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite and incomplete for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In particular, the current methods are incomplete in not reciting how and when one knows they have completed the invention, as recited in the preamble, such as when detection of what eating disorders is indicated when compared to some non-recited control value, and in which what a corresponding increase or decrease in BDNF levels means, if eventually measured, versus measuring some unknown "concentration", alone.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barde et al (U.S. Patent 5,180,820), in view of Kernie et al (2000; IDS Ref #AW).

Barde et al teach a method of using antibodies against BDNF to detect and/or measure amounts of BDNF in tissue or fluid samples (i.e.; as it relates to claims 7-8, which reasonably include serum/blood; col. 26, lines 28-44). Labeled antibodies against BDNF are also taught, such as use of anti-rabbit peroxidase labeled antibodies (e.g., cols. 40-42; as it relates to claim 9). In that Barde detects BDNF with antibodies, and discloses its use as a therapeutic agent for damage due to metabolic disease or nutritional deficiency (e.g., cols. 26, line 56- col. 27, line 3), the limitations of claim 10 are met by Barde's detection method of BDNF itself. However, although Barde disclose use of their antibodies in a detection method, and use of BDNF to treat patients with metabolic disease or nutritional deficiency, they do not explicitly teach detecting altered levels of BDNF in blood, or such being related to detecting one or more eating disorders.

Kernie et al teach that low BDNF levels leads to "features that parallel the human condition of obesity" (pg. 1296, 2nd col) and that administration of BDNF to the hypothalamus decreases weight in both obese and wildtype mice (pg. 1296, 1st col, pg. 1298 & Fig. 9). Kernie further teach that reduction of endogenous BDNF levels in the hypothalamus can result in eating behavior disorders. However, Kernie did not directly assay BDNF levels in blood using BDNF antibodies.

It would have been obvious to one of ordinary skill in the art to monitor BDNF levels using antibodies against BDNF, as taught by Barde, in body fluid samples, such as blood, in order to detect whether decreased BDNF levels indicate obesity in patients, and whether weight loss can be correlated with increase BDNF levels, as taught by Kernie.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Stucker, can be reached on (571) 272-0911. The fax phone number for this Group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Robert C. Hayes, Ph.D./
Primary Examiner, Art Unit 1649
March 24, 2008